510(k) Summary

MAY 17 2013

1. **Submission Sponsor**

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2. **Submission Correspondent**

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Contact: Carrie Hetrick, Senior Consultant, RA
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3. **Date Prepared**

April 26, 2013

4. **Device Identification**

Trade/Proprietary Name:	ScopeValet Disposable Biopsy Valves
Common/Usual Name:	Biopsy Valves
Classification Name:	Endoscope and accessories
Classification Regulation:	876.1500
Product Code:	OCX
Device Class:	Class II
Classification Panel:	Gastroenterology/Urology

5. **Predicate Devices**

EndoChoice – Seal™ Biopsy Valve (K111821)

6. **Device Description**

The Ruhof Corporation ScopeValet Disposable Biopsy Valves can be manufactured with a choice of two types - regular disposable biopsy valve and irrigating biopsy valve. Each of these types can be ordered for Olympus, Fujinon, and Pentax gastrointestinal endoscopes.

7. **Intended Use**

The ScopeValet Disposable Biopsy Valves are intended to provide access for endoscopic device passage and exchange, helps maintain sufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.

8. Substantial Equivalence Discussion

The following table compares the ScopeValet Disposable Biopsy Valves to the predicate device with respect to the intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Manufacturer	**Ruhof Corporation**	**EndoChoice, Inc.**
Trade Name	ScopeValet Disposable Biopsy Valves	Seal Biopsy Valves
510(k) Number	K122417	K111821
Product Code	OCX	OCX
Regulation Number	876.1500	876.1500
Regulation Name	Endoscope and accessories	Endoscope and accessories
Design	The ScopeValet disposable biopsy valve – non-sterile is used to cover the opening to the biopsy/suction channel inlet of Olympus® and Fujinon® (G5 series and newer), gastrointestinal endoscopes or for use with Pentax® gastrointestinal endoscopes. The ScopeValet disposable biopsy valve – non-sterile provides access for endoscopic device passage and exchange, helps maintain insufflation and minimizes leakage of bio-burden from the biopsy port throughout the gastrointestinal endoscopic procedure.	The EndoChoice biopsy valve can be manufactured with a choice of two types – regular disposable biopsy valve and irrigating biopsy valve. Each of these types can be ordered for Olympus, Fujinon, and Pentex gastrointestinal endoscopes.
Indications for Use	The ScopeValet Disposable Biopsy Valves are intended to provide access for endoscopic device passage and exchange, helps maintain sufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.	Biopsy valves are intended to provide access for endoscopic device passage and exchange, helps maintain sufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.
Compatible Endoscope(s)	Olympus and Fujinon, (G5 series and newer) gastrointestinal	Olympus and Fujinon, (G5 series and newer) gastrointestinal

Manufacturer	Ruhof Corporation	EndoChoice, Inc.
Trade Name	ScopeValet Disposable Biopsy Valves	Seal Biopsy Valves
	endoscopes or Pentax gastrointestinal endoscopes	endoscopes or Pentax gastrointestinal endoscopes
Patient Population	Patients who are undergoing an endoscopy	Patients who are undergoing an endoscopy
Environment	Hospital and/or Clinic	Hospital and/or Clinic
Manufacturing Method	Injection molded	Injection molded
Opening for Instruments	Slit in diaphragm	Slit in diaphragm
Material	TPE	TPE
Sterile	No	No
Single-Use, Disposable	Yes	Yes
Shelf Life	One (1) year	Not known
Complies with ISO 10993-1	Yes	Yes

9. Non-Clinical Performance Data

The following testing has been performed to support substantial equivalence:

- Leak testing – Leak testing was performed with the ScopeValet Disposable Biopsy Valves to simulate the withdrawal of biopsy samples, bowel irrigation and bowel insufflation. The ScopeValet Disposable Biopsy Valves revealed no evidence of fluid leakage during the sample biopsy or bowel irrigation. Thus, the ScopeValet Disposable Biopsy Valves are an effective means of preventing fluid leakage in gastrointestinal endoscopic procedures.

- Insufflation air flow rate testing - Tests were performed simulating bowel insufflations, whereby the ScopeValet Disposable Biopsy Valves tested maintained a pressure of at least 10 psi with no testing. The insufflation air flow rate is comparable to that of the predicate device, delivering enough air for insufflation in the time typically used for insufflation. Thus, the ScopeValet Disposable Biopsy Valves is an effective means of achieving insufflation in gastrointestinal endoscopic procedures.

- Biocompatibility – Biocompatibility testing of the ScopeValet Disposable Biopsy Valves was conducted in accordance with the ISO 10993-1 "Biological evaluation of medical devices" standards and FDA/CDRH/ODE Blue Book Memorandum G95-1, "Use of International Standard ISO 10993", 'Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing' using a representative device. Based on ISO 10993-1, the biopsy valves are body contact (mucosal membranes) and limited contact duration (less than 24 hours). The ScopeValet Disposable Biopsy Valves are made of thermoplastic elastomer (TPE) materials that are Generally Recognized As Safe (GRAS) materials according to ISO 10993 for cytotoxicity, sensitization, and irritation, are USP Grade VI, and the colorants are cleared (or FDA listed). The device was tested for cytotoxicity as per ISO 10993-5, and passed. The results and analysis demonstrate the ScopeValet Disposable Biopsy Valves are biocompatible as per ISO 10993-1.

- Shelf-life – Stability of the subject device was established from the results of physical testing data using a protocol.. Based on the evaluation of the results of the physical testing data, the expiring date has been set at one (1) year.

As part of demonstrating safety and effectiveness of ScopeValet Disposable Biopsy Valves and in showing substantial equivalence to the predicate device that is subject to this 510(k) submission, Rohuf Corporation completed a number of tests. The ScopeValet Disposable Biopsy Valves meets all the requirements for the overall design,and biocompatibility that the output meets the design inputs and specifications. The ScopeValet Disposable Biopsy Valves passed all testing stated above as shown by the acceptable results obtained.

The ScopeValet Disposable Biopsy Valves complies with the applicable voluntary standards for biocompatibility. The device passed all the testing in accordance with national and international standards.

10. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate device, have been on the market for many years with proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the difference between ScopeValet Disposable Biopsy Valves and the predicate device do not raise any questions regarding its safety and effectiveness. The ScopeValet Disposable Biopsy Valves, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 17, 2013

Ruhof Corporation
% Ms. Carrie Hetrick
Senior Consultant, RA
Emergo Group, Inc.
816 Congress Avenue, Suite 1400
AUSTIN TX 78701

Re: K122417
Trade/Device Name: ScopeValet Disposable Biopsy Valves, Models 345BVO and 345BVP
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCX
Dated: April 30, 2013
Received: May 1, 2013

Dear Ms. Hetrick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K122417

Device Name: ScopeValet Disposable Biopsy Valve, Model Numbers 345BVO and 345BVP

Indications for Use: The ScopeValet Disposable Biopsy Valves, Model Numbers 345BVO and 345BVP, are intended to provide access for endoscopic device passage and exchange, helps maintain sufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.

Prescription Use	AND/OR	Over-The-Counter Use _____
X		(21 CFR 801 Subpart C)
(Part 21 CFR 801 Subpart D)		

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122417